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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Maxwell Gordon

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,714	Applicant(s) GORDON, MAXWELL	
	Examiner Renee Claytor	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 16-18, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 16-18, 21-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Currently, claims 1-6, 16-18 and 21-22 are pending.

Response to Arguments

Applicants point out that claims 18 and 22 were not rejected and assume that the claims are free of the art. The Examiner would like to note that this was an inadvertent error in not listing the claims in the heading of the rejection but would like to point to the body of the rejection in which claim 18 is specifically addressed as being rejected (page 4 of the previous Office Action) and the Meissner reference was used to teach the method of treating constipation in which claim 22 is the only claim to this method. Therefore it is obvious that the claims were included in the rejection and are not considered free of the art.

Applicants argue over the 35 USC 103 rejection over Oshlack in view of Meissner. In particular, Applicants argue that Oshlack does not mention the ingredients of claim 1. It is further argued that the enteric coated pellets of the instant claims are not made obvious by Oshlack or Meissner. Applicants further argue that Meissner teaches titrating the amount of naloxone to determine the dose for treating or preventing constipation and makes each patient a research project and doesn't provide information as to how to make a dosage form.

In response to the above arguments, it is noted that claim 1 is drawn to a dosage form that comprises an opiate, an opiate antagonist and hydrocolloids and other excipients. As discussed in the rejection, Oshlack et al. render obvious such dosage forms because Oshlack teaches dosage forms comprised of an opiate and an opiate

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antagonist (Col. 6, lines 16-20). Oshlack et al. further teaches that gelling agents and other excipients are included in the composition including those as listed in claim 1 (Col. 7, lines 20-47; Col. 16, lines 48-55 and Example 6). Therefore Oshlack et al. does teach the elements of claim 1 and renders the dosage form obvious. Further, Oshlack et al. renders obvious the enteric coated pellets because the reference teaches coated beads that can contain the opiate, the opiate antagonist and hydrocolloid and excipients which can be formulated into a controlled and immediate release formulation. The purpose of the Meissner reference was to teach the method of improving laxation during naloxone treatment and does not concentrate on the dosage form.

Accordingly, the rejection is maintained and given below for Applicant's convenience.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 16-18 and 21-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US Patent 7,144,587) in view of Meissner et al (Pain 84, 2000, 105-109).

Oshlack et al. teach solid dosage forms of compositions comprised of an opiate, an opiate antagonist and a hydrocolloid containing excipient (meeting the limitation of

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claim 1; Col. 6, lines 16-20). More specifically the opiates are chosen from agents such as morphine, codeine and oxycodone (meeting the limitation of claims 2-3; see Col. 12, lines 34-56 for a more complete list). Antagonists that are useful in the invention include naltrexone and naloxone (meeting the limitation of claims 4-5; lines 14-15). Dosage forms are taught that include coated beads including the composition (meeting the limitation of claim 6; Col. 17, lines 23-61). In regards to the limitation that the amount of the enteric coated opiate antagonist pellets is effective to prevent opiate induced constipation, it would be obvious that because Oshlack et al. teach coated beads, it would necessarily prevent opiate induced constipation. It is taught that gelling agents or other excipients are included in the dosage forms, which include starch and starch derivatives, lactose, xanthan gum, locust bean gum, microcrystalline cellulose, alginates, dicalcium phosphate (dibasic calcium phosphate) and magnesium stearate (Col. 7, lines 20-47; Col. 16, lines 48-55 and Example 6). It is noted that the teaching of dicalcium phosphate renders the monocalcium phosphate obvious because the compounds are similar and have similar properties of being excipients. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the Applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). The gelling agents impart a gel-like quality to the dosage form if it is tampered with and prevent abuse of the dosage form by minimizing absorption (Col. 7, lines 48-55). It is further taught that when the dosage form is tampered with and exposed to a small amount of a liquid such as water, the dosage form will be unsuitable for injection (meeting the limitation of claim

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18; Col. 3, lines 12-16). Table 1 exemplifies a composition comprised of oxycodone with naloxone. Further, Oshlack et al. teaches that the opiate/opioid antagonist formulation together with a hydrocolloid can be formulated in immediate release formulations or controlled release in any suitable tablet (Col. 17, lines 12-15), and teaches coated beads that can contain the opiate, the opiate antagonist and hydrocolloid. Therefore, it would be obvious that one tablet could contain beads that are controlled and immediate release (meeting the limitation of claim 16-17). Further, because Oshlack et al. teach compositions comprised of the same components, it would be obvious that the composition would be released in the same areas, such as the colon (further addressing claim 16).

Oshlack et al. does not specifically teach a compound comprised of all the ingredients listed in claim 1 nor does it teach that the composition is used in a method of treating constipation.

Meissner et al. teaches improved laxation during oral naloxone treatment in opioid-associated constipation (see whole document).

Accordingly, it would be obvious to a person having ordinary skill in the art at the time of the invention to formulate a composition comprised of an opiate, an opiate antagonist, hydrocolloids and other excipients as exemplified in claim 1 because Oshlack et al. teach the suitability of all of the hydrocolloids and excipients in a composition of coated beads with an opiate and an opiate antagonist. One would be motivated to include the hydrocolloids and excipients in the composition in an effort to form a composition that when tampered with will impart a gel-like quality to avoid abuse

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of the opiate composition (as taught by Oshlack et al., Col. 7, lines 48-55). One would be further motivated to use the composition in a method of treating constipation associated with the use of opioids because of Meissner's teachings that the combination of an opioid agonist and antagonist effectively treats constipation induced by the opiate.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

**/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617**